

Serial No. 10/025,977
CATT-001REMARKS UNDER 37 CFR § 1.116Formal Matters

In the Advisory Action dated August 24, 2004, the previously presented rejections of claims 9-13, 15-18 and 30-38 were maintained. In response to the Advisory Action, a response was filed along with a Request for Continued Examination on October 21, 2004, which was subsequently granted. On January 12, 2005, a telephonic Interview was held between the undersigned and Examiners Landrem and McDermott in which the relevance of the previously cited art with respect to the previously presented claims was discussed. Applicant thanks the Examiners for their participation in the Interview. Complete agreement was not reached as to the patentability of the previously pending claims. As such, Applicant provides the present Amendment and the following remarks.

By this Amendment, claims 9, 30, 35 and 36 have been amended and claims 39-41 have been added. The claim amendments are fully supported in the specification, the drawings and the originally filed claims. Accordingly, no new matter has been added.

Claims 9-13, 15-18 and 30-41 are pending in the application. Claims 1-8, 14 and 19-29 were previously cancelled.

Rejections Under 35 U.S.C. §103

Claims 9-13, 15-18 and 30-38 were previously rejected under 35 U.S.C. §103(a) as being unpatentable over Kuehn et al. (USPN 6,165,183) in view of Cribier et al. (USPN 4,777,951).

Claim 9, as well as claims 10-13, 15-8, 30-41 by virtue of their dependency on claim 9, are directed to a method of repairing cardiac valves using an apparatus comprising a fastener element which is releasable from the apparatus and is used to both temporarily grasp (step b) and permanently secure (step e) together the leaflets of a cardiac valve. As the claim language provides, the releasable fastener element is adapted to temporarily grasp and release the valve leaflets. As such, the user may elect to grasp the leaflets only temporarily (and subsequently release the fastener element from the leaflets) or grasp the leaflets permanently by releasing the fastener from the apparatus. The current amendments to the claims have been made to emphasize this functionality and structure of the fastener element. The claimed method is further directed to determining whether to permanently secure valve leaflets at a selected apposition

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point based upon the measured blood flow and/or the pressure gradient through the valve when the fastener is temporarily grasping the valve's leaflets at the apposition point (step d).

None of the fasteners disclosed by Kuchn et al. are capable of performing both of the claimed functions where a single element is used to temporarily grasp the leaflets and to permanently grasp the leaflets. To reiterate a previous argument presented by the Applicants, reference is made to the embodiment of Figs. 13A-F in Kuehn et al. While Kuehn et al. describes this instrument as "a single element gripper/fastener", the "element" (which consists of gripper arms 256, 258, 260, 262 and a locking mechanism) is not configured to temporarily grasp and then release the leaflets, i.e., once deployed from sleeve 254 onto the leaflets, the element cannot be unfastened from the leaflets. This is supported by at least the text in Kuchn et al. from col. 7, line 65 to col. 8, line 3: "Referring to Fig. 13E, end 272 of inner core 264, while gripping and fastening leaflets 122, 124, is released from the remaining portions of inner core 264 by disengaging a locking mechanism thereby securing the leaflets with the fastening device. Inner core 264 is removed through cardiac catheter 126." The underscored text implies that the locking mechanism is employed on the element while fastening as well as gripping the leaflets, i.e., the element is meant to grip and be permanently fastened to the leaflets with a single application. That the inner core is removed upon the gripping/fastening step further supports this. Thus, the nomenclature "gripper/fastener" as used by Kuchn et al. in the context of describing its single element device describes an element which is only capable of performing a single, discrete action, i.e., permanent grasping/fastening to the valve leaflets, and not the two separate actions of temporarily gripping and permanently fastening.

As with the above discussed single element fastener of Kuehn et al., none of the other fastener embodiments disclosed by Kuehn et al. are able to both temporarily and permanently grasp the leaflets. Support is not found to the contrary in the Examiner's reference to the disclosure in Kuehn et al (8:67-9:4) which states (with reference to Figs. 16 and 17) that "gripper 402 can grab leaflets 122, 124. Then, fastener 404 can be opened in the withdrawn position and slid forward to apply a tack on the captured leaflet edges." This embodiment and its use are distinguishable from the claimed invention in at least the following ways. First, this embodiment does not use a single element which is adapted to both temporarily grasp the leaflets and permanently fasten the leaflets together (as required by (a) and (c) of claim 1). Instead, it employs two separate elements, one for each function: the grasper 402 to temporarily grasp and

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the tack to permanently secure. Second, Kuehn's grasper is not releasable from the apparatus which delivers and operates it (shaft 406) (as required by (a) of claim 1). Third, the grasper is also not able to permanently secure the leaflets (as required by (e) of claim 1). Fourth, Kuehn's tack is not capable of temporarily grasping the leaflets, only permanently penetrating them (as required by (a) of claim 1).

In addition to not disclosing the above-discussed elements of the claims, Kuehn et al. do not disclose the step of measuring at least one of blood flow and pressure gradient across the valve while the releasable fastener element is grasping the leaflets (step (c)) nor the step of determining whether to permanently secure the valve leaflets at the selected apposition point based upon at least one of the measured blood flow and pressure gradient, the latter also being performed while the releasable fastener element is grasping the leaflets (step (d)). Having the capability to temporarily grasp and then release the leaflets is extremely useful in effecting an optimal end result (i.e., greatly improved cardiac function) based on steps (c) and (d) of the claimed invention. In addition to not disclosing these steps, Kuehn et al. does not disclose, suggest or recognize any need or benefit in temporarily grasping the leaflets.

Cribier et al. are cited for their teaching of measuring the pressure gradient across a valve during an aortic valvuloplasty. Cribier et al. do not teach or suggest anything about applying fasteners or the like to valve leaflets and measuring across the valve to determine the effectiveness of the fastening site on the leaflet. Accordingly, Cribier et al. do not make up for the deficiencies of the disclosure provided by Kuehn et al. Notwithstanding such, Applicants further submit that Cribier et al. actually teach away from the steps contemplated by (c) and (d) of the claimed invention.

The valvuloplasty procedure disclosed in Cribier et al. involves the use of an inflatable balloon to displace plaque on the valve leaflets to increase the effective flow cross-section of the stenosed valve. The balloon is repeatedly inflated and the pressure gradient measured across the valve between inflations to determine effective flow. When the measured pressure gradient reaches a satisfactory value, the procedure is terminated. It is noted that the balloon is withdrawn from the valve when the pressure gradient is being measured (see col. 3, lines 56-61). In at least this way, steps (c) and (d) of the claimed invention are distinguishable from the method of Cribier et al. as the blood flow and/or pressure gradient measurements and the determination as to whether to permanently secure the valve leaflets at the selected apposition

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point based upon the measurement taken are performed while the releasable fastener element is grasping the leaflets. In the Cribier et al. method, the balloon is removed from the valve when the pressure gradient is being measured.

For at least the reasons discussed above, neither Kuehn et al. nor Cribier et al. nor the combination thereof disclose, teach or suggest the claimed method. Accordingly, Applicants respectfully request withdrawal of this rejection and allowance of the claims.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CATT-001.

Respectfully submitted,
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